January 18, 2024

NuvoAir AB
Daniel Keenan
Senior Product Director, Medical Device
17D Riddargatan Stockholm, SE 11457
Stockholm, 11457
Sweden

Re: K231416
Trade/Device Name: Air Next
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: December 11, 2023
Received: December 11, 2023

Dear Daniel Keenan:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,

Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231416

Device Name
Air Next

Indications for Use *(Describe)*
NuvoAir Air Next is intended to test lung function and spirometry in adults and children 5 years of age and older.
It can be used in hospitals, in the clinical setting, and at home.
The Air Next is not intended for use in an operating room.
The user is not intended to interpret or take clinical action based on the device output without consultation of a qualified healthcare professional.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date of Summary Preparation:	January 18, 2024
510(k) submitter & owner	NuvoAir AB 17D Riddargatan Stockholm, SE 11457
Contact person	Owner & contact for 510(k) submission: Furat Shawki- General Manager, CT furat.shawki@nuvoair.com (+44)755 188 3598
Common name of the device	Spirometer
Trade name	Air Next
Model number	NVD-02
Classification **Classification name** **Product code** **Review panel** **Regulation number**	Class II Device Diagnostic Spirometer BZG Anesthesiology 21 CFR 868.1840
Predicate device **510(k) number** **Trade name** **Product code** **Manufacturer**	 K072979 Spirobank G BZG MIR Medical International Research

Device Description

Air Next is intended to perform basic lung function and spirometry testing. It measures parameters such as the forced expiratory volume in 1 sec (FEV1) and the forced vital capacity (FVC) in a forced expiratory maneuver. These measures can be used for detection, assessment and monitoring of diseases affecting the lung function, such as bronchial Asthma, COPD and Cystic Fibrosis.

Air Next is a hand-held spirometer, weighing 75g and it is powered by 2 AAA alkaline 1.5V batteries. It consists of 3 main components: the Air Next device, the NuvoAir disposable turbine (delivered in one package) and the Air Next mobile application downloadable from Apple's and Google's Play Stores.

Indications For Use

NuvoAir Air Next is intended to test lung function and spirometry in adults and children 5 years of age and older.

It can be used in hospitals, in the clinical settings, and at home.

The Air Next is not intended for use in an operating room.

The user is not intended to interpret or take clinical action based on the device output without consultation of a qualified healthcare professional.

Predicate	K Number	Brand Name	CE Certificate	Company
Primary	K072979	Spirobank G	93/42/EEC Certified No: MED 9826 NoBo:0476 Valid until: 2023-02-04	MIR Medical International Research
Reference	K061712	Spirobank II		MIR Medical International Research
Product Code		BZG	**Regulation No**	21 CFR 868.1840

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO PREDICATE DEVICE

Characteristics	NuvoAir Air Next	Spirobank G K072979	notes
Manufacturer	NuvoAir	MIR Medical International Research	
Regulation Number	21 CFR 868.1840	21 CFR 868.1840	Same
Product Code	BZG	BZG	Same
Indications for Use	NuvoAir Air Next is intended to test lung function and spirometry in adults and children 5 years of age and older. It can be used in hospitals, in the clinical setting, and at home. The Air Next is not intended for use in an operating room. The user is not intended to interpret or take clinical action based on the device output without consultation of a qualified healthcare professional.	The Spirobank G spirometer is intended to be used by a physician or by a patient under the instruction of a physician or paramedic. The device is intended to test lung function and can make spirometry testing in people of all ages, excluding infants and neonates. It can be used in any setting.	Similar

Type of Use	Prescription Use	Prescription Use	Same
User Environment	Hospitals, in the clinical setting, and at home.	In any setting	The use environment for the subject device is a subset of the predicate device use environment.
Principle of Operation	The Air Next is designed to work with NuvoAir disposable turbine. When performing a spirometry test, the user exhales into the turbine. The airflow generated is forcing a propeller to rotate inside the turbine. The Air Next registers the speed of the spinning propeller by counting the rotations with a digital infrared interruption sensor. The algorithm in the firmware inside the Air Next device then converts the rotations into airflow measured in liters per second. This widely spread technology circumvents the need for individual calibration by exploiting mechanical properties of the turbine, which are verified and calibrated at the time of	Spirobank G is a powerful and compact measurement device, intended for use by a respiratory specialist or by a suitably trained generalist. Two different types of turbine sensors can be used with the device, one is reusable and one is single-patient disposable. A disposable mouthpiece is required in order to connect a subject to the spirometer. The flow and volume measurement sensor is a digital turbine, based on the infrared interruption principal. Cleaning of the disposable turbine is not required, as it is supplied clean in a sealed plastic bag. It must be disposed of after use.	Substantially equivalent (SE). Differences do not raise new or different questions of safety or effectiveness
Flow Sensor	Bidirectional turbine with infrared interruption	Bidirectional turbine with infrared interruption	Same
Energy Type	Two AAA 1.5V Alkaline	9V Alkaline battery	SE

	batteries		
Display	Touchscreen on smartphone or tablet	Touchscreen / LCD and membrane keys 128 x 48 pixel, graphic LCD - FSTN	Similar
Operating Environment	T: min +10°C/max +40° C RH: min 10 %/max 95 % ALT: max 2000 m	Temperature: MIN + 10 °C, MAX + 40 °C; Humidity: MIN 10% RH; MAX 95%RH	Same
Physical Size	Light hand-held device	Light hand-held device	Same
Weight	75g	160g	Differences do not raise new or different questions of safety and effectiveness
Volume accuracy	±3% of reading or ±0.050 L, whichever is greater	±3% of reading or ±0.050 L, whichever is greater	Same
Volume range	Up to 10 L	Up to 10 L	Same
Flow range	0-15L/s	0-16 L/s	Similar
Flow accuracy	±5% or 200 mL/s	±5% or 200 mL/s	Same
Flow resistance	<0.5 cmH2O/L/s	<0.5 cmH2O/L/s	Same

Characteristics	NuvoAir Air Next	Spirobank G K072979	notes
Connectivity	Bluetooth	Bluetooth or USB	Same-Bluetooth
Forced vital capacity	FVC	FVC	Same
Volume expired in the first 0.75sec, 1sec, 3sec, 6sec	FEV0.75, FEV1, FEV3, FEV6	FEV0.75, FEV1, FEV3, FEV6	Same
Ratio between volume expired in a certain time period and FVC	FEV/FVC (FER) for 0.75 /1 /3 / 6	FEV/FVC (FER) for 0.75 /1 /3 / 6	Same
Peak expiratory flow	PEF	PEF	Same
Forced expiratory flow between the first 25% and 75% of the FVC	FEF25-75 (MEF)	FEF25-75 (MEF)	Same
Volume inspired in the first second of the test	FIV1	FIV1	Same
Forced inspiratory volume	FIVC	FIVC	Same
Peak inspiratory flow	PIF	PIF	Same
Forced inspiratory flow in the first 25% and 75% of the FIV	FIF25-75 (MIF25-75)	FIF25-75 (MIF25-75)	Same
Ratio between FEV1 and FEV6	FEV1/FEV6	FEV1/FEV6	Same
Forced expiratory flow at 50% of FVC divided by FVC	FEF50/FVC	FEF50/FVC	Same

Characteristics	NuvoAir Air Next	Spirobank G K072979	notes
Forced inspiratory flow in the first 25% and 75% of the FIV	FIF25-75 (MIF25-75)	FIF25-75 (MIF25-75)	Same
Ratio between FEV1 and FEV6	FEV1/FEV6	FEV1/FEV6	Same
Forced expiratory flow at 50% of FVC divided by FVC	FEF50/FVC	FEF50/FVC	Same
Force inspiratory flow at first second device forced inspiratory volume	FIV1/FIVC (FIR)	FIV1/FIVC (FIR)	Same
Forced expiratory time	FET	FET	Same
Maximum voluntary ventilation	**N**/A	MVV (ind)	Different but the difference does not affect safety or effectiveness
Used with PFT filter and / or mouthpiece	Mouthpiece Disposable	Mouthpiece Disposable or Reusable	Same for Disposable Turbine – See reference predicate chart below
Coaching	Display of volume-time and flow-volume curves, timer and effort during test	Display of volume-time and flow-volume curves	The main difference is that in the subject device the user can observe a real-time feedback on the effort of the spirometry test, while this feature is missing on the predicate device. This difference does not raise new or different questions of safety or

			effectiveness
Feedback on test quality	Yes - according to ATS 2019 guidelines	Yes – Traffic lights for interpretation	This difference does not raise new or different questions of safety or effectiveness
Graphic display	Yes- on App	Yes on device screen	Different but the difference does not affect safety and effectiveness
Meets ATS accuracy requirements	Yes	Yes	Same
Applied Standards for safety	Electrical Safety Standard IEC 60601-1 Electro Magnetic Compatibility IEC 60601-1-2	Electrical Safety Standard IEC 60601-1 Electro Magnetic Compatibility IEC 60601-1-2	Same
Water ingress protection	IP32	IPX1	SE

Biological characteristics	**NuvoAir Air Next**	**Spirobank G** K072979	**Identified differences**
Uses the same materials or substances in contact with the same human tissues or body fluids and leachables	Plastic Covers: ABS-PC body contact: hand held	Plastic Covers: ABS-PC body contact: hand held	Same
Similar kind and duration of contact with the same human tissues or body	surface medical device, in contact with intact skin	surface medical device, in contact with intact skin	Same

fluids			
Similar release characteristics of substances including degradation products	limited contact duration	limited contact duration	Same
Biocompatibility	According to ISO 10993-1	According to ISO 10993- 1	Same

- **Turbine:**

The disposable turbine used in the reference predicate device (K061712) is the same as the disposable used in the subject device.

- **Compliance with Standards**

Air Next complies with the currently recognized safety and EMC standards:

- IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 -- Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 62366:2007 – Medical devices — Application of usability engineering to medical devices
- 60601-1-2:2014 (ED. 4) – Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ETSI's EN 300 328 v.1.9.1 – Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive
- FCC Part 15, Subpart B, C Unintentional Radiators, Intentional Radiators
- Standardization of Spirometry 2019 Update. An Official American Thoracic Society and European Respiratory Society Technical Statement
- ISO 23747:2015 -- Anaesthetic and respiratory equipment – Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans
- ISO26782:2009 -- Anaesthetic and respiratory equipment – Spirometers intended for the measurement of time forced expired volumes in humans
- IEC 60601-1-11:2015 – Medical Electrical Equipment–Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-1-6:2010 + A1:2013. Medical electrical equipment– Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- ISO 62304:2006/A1:2015: Medical device software. Software life cycle processes
- ISO 14971:2007. Application of risk management to medical devices
- ISO 15223-1:2021 – Medical devices Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements
- ISO 20417:2021 – Medical devices Information to be supplied by the manufacturer

Biocompatibility

Handle and Exterior Surface

The Handle and Exterior is designed to be a surface device for intact skin with limited contact A – limited (≤24h). The following testing was performed:

Based on the device categorization outlined above, the nature of the material contact and the guidance given in ISO 10993-1, the tests deemed appropriate for the device materials were selected as shown in the table below.

Biological Effect	**Test**	**Compliance Standard**
Cytotoxicity	Mem Elution	ISO10993-5
Irritation or Intracutaneous Reactivity	Intracutaneous Injection Test	ISO10993-10
Irritation and Sensitization	Kligman Maximization test	ISO10993-10

Substantial Equivalence Conclusion

Based upon the foregoing performance testing and comparison to the legally marketed predicate devices for indications for use, technology, and performance the Air Next is substantially equivalent and as safe and as effective as the predicate device.